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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,950	11/25/2003	Russell Alan Parker	10030712-1	9616

22878 7590 03/22/2006

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EXAMINER

PADGETT, MARIANNE L

ART UNIT PAPER NUMBER

1762

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/722,950

Applicant(s)

PARKER ET AL.

Examiner

Marianne L. Padgett

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 March 2006.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,16-18,27-29,53-55 and 57-62 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1,16-18,27-29,53-55 and 57-62 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/2/2006 has been entered.

2. The amendments in the 1/31/2006 after final removed 112 problems (set forth in the 11/2/05 rejection) as discussed in the advisory action of 2/13/06, while the amendments of 3/2/2006 corrected problems as noted in that advisory action, plus have added limitations that positively require the claimed backing element comprising a gasket to be employed with/for and array assay chamber.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 16-17, 28, 53-54, 57-58 & 61 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Audino et al. (2002/0083686 A1).

Audino et al (abstract; figures, especially 4-5b; [0002]; [0003-9] for background and problems; [0010]; [0020-21]; [0024-29]) teach a sealing member (i.e. gasket) made of an elastomeric material, which is employed to create a seal between a lid and a multi-well plate (microtiter test plate) that may be used in biological or chemical assays. The sealing member structure may be melt welded/sealed (i.e. joined) to the multi-well storage or test plate, or to the lid. Various structures, materials and means for producing elastomeric sheet sealing member are taught inclusive of multilayered structures, where an example for sealing polypropylene plates was given as using a polypropylene film or compatible material which is corona treated on one side, where it is noted that corona treatment is a species of plasma treatment (an analogous process for polystyrene film was also disclosed). The corona treated side was taught to be coated with a layer of partially epoxydized polybutadiene which is polarized to form a cross-linked monomer that is bonded to the thermoplastic film ([0028]), hence reading on the options of both depositing a material on the gasket structure and on the elected species of plasma modifying the surface of the gasket structure.

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5. Claims 18, 27, 55 & 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Audino et al.

Audino et al do not teach what gases are employed when they corona treat their sealing members' surface, nor do they discuss whether or not the hydrophilicity of the surface is increased, however corona discharge processes are commonly done under atmospheric conditions, i.e. in air, hence it would have been obvious to one of ordinary skill in the art, that when no particular gases are disclosed as in Audino et al, to employ typical or old and well-known conditions for the taught corona process, and therefore to employ air in the treatment. It is further noted that since oxygen in the air is a major reactive component, that it would have been expected to effect oxygen functionalization of the polymeric surfaces so treated, which would have increased their hydrophilicity, especially for the exemplified polypropylene or polystyrene films whose initial structures contain no oxygen, so that the taught corona treatment thereof would have been expected to increase the hydrophilicity and thus increase the wettability of the coating that is applied thereafter.

6. Claims 29 & 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Audino et al as applied to claims 1, 16-18, 27-28, 53-55 & 57-61 above, and further in view of Gilmore et al. (2003/0207099 A1, previously discussed in section 8 of the 11/2/2005 action).

Audino et al does not teach treating the sealing member surface (gasket) with sequential treatments of at least two treatments chosen from the group of plasma, or UV + O<sub>2</sub>, or a solvent. However, it is noted that since there is cleaning procedures such as washing which uses solvents are standard procedures in coating operations it would've been obvious to one of ordinary skill and competence to clean, as by washing, the polypropylene or polystyrene surfaces of the sealing member before the corona treating and coating operations, as a matter of standard practice to ensure improved coding adherence due to removal of any contaminants.

Alternately, Audino et al also teaches the use of other materials, such as silicones (although less desirable, [0028]), hence it would have been obvious to one of ordinary skill in the art to employ treatments known to improve the wettability of silicone surfaces, such as those taught by Gilmore et al. (abstract; [0010-14]; [0025-28, esp.28]; & esp. [0030] + [0032]) for improving the wettability of silicones polymer membranes, such as polydimethylsiloxane (PDMS), in order to enable equivalent usability with the exemplified polypropylene or polystyrene. It is noted that Gilmore et al. teaches a process with two consecutive plasmas (e.g. O<sub>2</sub> plasma, then SiCl<sub>4</sub> plasma) to enhance and stabilize the wettability of PDMS membrane materials by hydrophilizing the surface, to enable subsequent coating/adhesion.

7. Claims 1, 16-18, 27-29 & 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desrosiers et al. (6410332 B1) or Dunnington et al. (6376256 B1) or Stanchfield et al. (6054100), in view of Matsuzawa et al (JP2000-300670 A)

The primary references to Desrosiers et al. (6410332 B1) or Dunnington et al. (6376256 B1) or Stanchfield et al. (6054100) all teach the use of gaskets for joining multi-well structures for chemical sampling and analysis or synthesis, i.e. chemical reactions, where Desrosiers et al. (abstract; figures to & 5-6, reference numbers 64 & 72, 188, 238, respectively; column 7, lines 57-column 8, line 4; column 10, lines 23-29; and column 11, lines 24-30) teach that the gasket material can be any inert, resilient material that provides to stress relief and helps prevent migration of reaction mixture between components of the library members, i.e. between the wells; or where Stanchfield et al. (abstract; figures 1 & 12, reference numbers 18 & 20, or 106 & 108, respectively; column 6, line 65-column 7, line 7; column 8, line 35-40; column 9, line 55-column 10, lines 5, 13-26 & 56-65; column 11, lines 28-53, especially 45-50) teach the gaskets to be chemically resistant rubber materials as are well known to be used for forming septa for sealing of containers by researchers e.g. VITON or SANTOPRENE; or where Dunnington et al. (abstract; figures 1 & 12, reference numbers 17, or 128 & 130, respectively; column 4, lines 28-32; column 9, lines 46-68) teach gaskets or elastomeric sheets made preferably of chemically resistant fluoroelastomer such

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as material available under the trademark VITON. However, none of these references give any details or more specific discussion on how the gasket or sealing member is formed or prepared, but all of these primary references suggest the need for chemically resistant materials, resilient materials and either chemically inert or fluoroelastomeric materials, thus providing guidance to one of ordinary skill on suitable materials for use as gaskets.

Matsuzawa et al, as discussed in the abstract & in the machine translation, provide a means for making rubber gaskets useful with syringes, that have satisfactory sealing properties with respect to medicinal fluids, hence relevant to the primary references for its stability to seal and protect against fluids contained in a cellular compartment. In the translation [0002] indicates gasket materials fabricated out of thermoplastic elastomers, with [0003] noting useful list of fluororesins. [0007], [0015-16] & abstract discuss that after a rubber gasket is molded or fabricated in an appropriate shape, it is plasma treated with at least one plasma gas of H<sub>2</sub>, N<sub>2</sub>, O<sub>2</sub>, F<sub>2</sub>, a fluoride or an "inactive" gas; thereafter it is exposed to a plasma of a hydrocarbon gas. In [0010] notes the outstanding chemical stability of the produced gasket such that it prevents pollution due to migration of solutions contained by the syringe and gasket, while in the part of paragraph [0011] at the top of p.3 & [0013], desirable physical properties for the completed gasket are discussed, including appropriate deformability for use as a gasket. Therefore, it would have been obvious to one of ordinary skill in the art to employ gasket forming procedures as suggested by Matsuzawa et al to create specific configurations as desired in any of the primary references, in order to provide a gasket with satisfactory sealing properties in the presence of fluids, as well as suitable deformability or resilience. Note that the use of 2 separate plasmas can be considered to read on the "at least two" choice of claims 29 & 62, while the use of O<sub>2</sub> on the rubber would have been expected to increase the hydrophilicity of the rubber surface.

8. Claims 1, 16, 28, 53, 57 & 61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims one & 15-17 of copending

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Application No. 10/172.850 (Arthur Schleifer). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are so broad as to encompass the curing claimed in the application to Schleifer, since while the semantics are different, the configurations of the gasket and assay chamber of the two cases are of overlapping scope, and the curing process applied to the gasket material of Schleifer can be considered to be read on by the claimed treating options of the present case, because the curing will modify the surface of the deposited gasket. As presently claimed the overlapping scopes may be considered obvious variations.

It is noted that 10/172.850 (Arthur Schleifer), while by a different inventor appears to be to the same assignee as shown by the patent application publication 2003/0231985 A1 of this application, hence rejection under obviousness type double patenting is appropriate. As the filing date of this application (6/14/2002) is before the present filing date of 11/25/2003, and there are no overlapping inventors rejection under 102/103 is also appropriate, at this time.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1, 16, 28, 53, 57 & 61 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Arthur Schleifer (2003/0231985 A1), as discussed above in section 8.

10. Other art of interest include Tsai (2005/0098032 A1) and Barth et al. (6682702 B2) previously cited in an IDS, which have teachings on relevant micro arrays for SA chambers that employ gaskets in configurations claimed; and Goldman et al. (2004/020934981), who teach arrays of test compartments with a sealable cap containing a gasket, where it's taught that the gasket is preferably hydrophobic.

11. Applicant's arguments with respect to claims 1, 16-18, 27-29, 53-55, 57-62 have been considered but are moot in view of the new ground(s) of rejection.



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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne L. Padgett whose telephone number is (571) 272-1425. The examiner can normally be reached on M-F from about 8:30 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks, can be reached at (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MLP/dictation software

3/16-17/2006



MARIANNE PADGETT  
PRIMARY EXAMINER